

**JUL - 5 1996**

**510(k) SAFETY AND EFFECTIVENESS SUMMARY**

Prepared: June 19, 1996

**K960888**

Submitter: Bayer Corporation, Business Group Diagnostics

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Device: Trade/Proprietary Name: CHEK-STIX U.T.I. Test Strips for  
the Detection of Urinary  
Tract Infection  
Common/Usual Name: Test for nitrite in urine  
Test for leukocytes (WBC's)  
in urine

Document Control Number: K960888

Classification Information: Division of Clinical Laboratory Devices  
Panel - Clinical Chemistry and Toxicology  
Classification Codes -- CH(75) JMT [Diazo (Colorimetric),  
Nitrite (Urinary, Non-Quant.)]  
CH(75) LJX (Urine Leukocyte Test)

Predicate Device: MULTISTIX® 2 Reagent Strips for Urinalysis  
Manufactured by Bayer Corporation

Device Description: CHEK-STIX U.T.I. Test Strips for the Detection of  
Urinary Tract Infection is a plastic strip to which is affixed  
two reagent pads to test for nitrite and leukocytes (WBC's)  
in a urine specimen. The product is provided as a carton  
containing a bottle of five strips and a package insert.

Intended Use: CHEK-STIX U.T.I. Test Strips for the Detection of  
Urinary Tract Infection is an O.T.C. home use test for  
nitrite and leukocytes (WBC's) in urine. It is intended to  
be used by lay persons to detect urinary tract infections.

Technological Characteristics:

CHEK-STIX U.T.I. Test Strips are dry reagent strips which, when in contact with a urine specimen, reacts with nitrite and leukocyte esterase in the specimen to give a pink and a purple color. The color of the strip is compared to a color chart on the bottle label to obtain the result. CHEK-STIX U.T.I. has the same test pads as are on strips used by doctors and clinical labs.

Assessment of Performance:

A study was conducted in clinical settings to demonstrate that lay persons can obtain results with CHEK-STIX U.T.I. comparable to results obtained by health care professionals.

Agreement between the two groups was 97% for the nitrite test and 85% for the WBC test.

Conclusion:

The results of the patient-use evaluation demonstrate that lay persons can use CHEK-STIX U.T.I. Test Strips and obtain results that are in agreement with results obtained by health care professionals. The instructions are simple to understand and afford the home user a way to detect urinary tract infections.